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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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08/983,474      06/30/98      KLATZMANN

D      GUPLA-0007

EXAMINER

HM22/0427

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BASIC  
ART UNIT

PAPER NUMBER

1646  
DATE MAILED:

04/27/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/983,474**

Applicant(s)  
**KLATZMAN et al**

Examiner  
**Nirmal. S. Basi**

Group Art Unit  
**1646**



☒ Responsive to communication(s) filed on Jan 20, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-18, 20, and 22-26 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 1, 3, 4, 20, 23, and 26 is/are allowed.

☒ Claim(s) 2, 5-18, 22, 24, and 25 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

### DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1646.

- 5        2.        Amendment filed 6/30/98 has been entered.
3.        Applicant's election with traverse of species C (claim 7), readable on claims 1-4, 7-18, 20 and 22-26, in Paper No. 8 (2/22/99) is acknowledged. The traversal is on the grounds that the three species relate to single general inventive concept is found persuasive and the species of claims 5-7 have been rejoined. Claims 1-18, 20 and 22-26 are pending and will be examined.

10            The requirement is still deemed proper and is therefore made FINAL.

### *Specification*

4.        This application is informal in the arrangement of the specification.

15            This application must include an Abstract of the Disclosure: A brief narrative of the disclosure as a whole in a single paragraph of 250 words or less on a separate sheet following the claims. Abstract of the Disclosure is not present in instant application.

Appropriate correction is required.

The oath or declaration submitted 10/28/98 (paper number 6) is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

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The oath or declaration is defective because: the date is incomplete, the applicant has written "8 X" to indicate month and day.

Appropriate correction is required.

**Claim Rejection, 35 U.S.C. 112**

5        5.        Claims 2, 5-13, 15-18 and 25 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

             Claims 2 and 22 are indefinite as it is not clear which SEQ ID NO: amino acids 493-549, 176-235, 510-549, 199-235, 498, 510, 185 and 199 are referring to. The afore mentioned  
10        fragments must be refereed to by SEQ ID NO:.

             Claim 5 is indefinite as it is not clear which combinations "and combinations" is referring to so as to allow the metes and bounds of the claim to be determined.

             Claim 6 is indefinite as it is not clear if the antibodies have a specificity for anti-Rh(D) or a specificity similar to that possessed by anti-Rh(D).

15        Claim 7 and 11 are indefinite as it is not clear what is a vaccinating antigen. Vaccinating antigen has not been define in the specification nor claims so as to allow the metes and bounds of the claim to be determined.

             Claim 8 and 10 are indefinite as it is not clear what is a therapeutic enzyme. Therapeutic enzymes has not been define in the specification nor claims so as to allow the metes and bounds of  
20        the claim to be determined. It is not clear what is the enzyme a therapeutic for.

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Claim 9 is indefinite as it is not clear what is a CD4 derivative. CD4 derivative has not been define in the specification nor claims so as to allow the metes and bounds of the claim to be determined. It is not clear what the derivative includes and excludes.

Claim 10 and 12 are indefinite as it is not clear what are the “ligand property” so as to  
5 allow the metes and bounds of the claim to be determined.

Claim 11, line 2, “contain” should be changed to “containing” to be grammatically correct.  
Claim 11 the terms “- in A” and “- in B” are confusing. Omitting said terms would make the  
claim clearer. Claim 11 indefinite as it is not clear what is “a derived molecule” so as to allow the  
metes and bounds of the claim to be determined. What is the derived molecule and what is it  
10 derived from?

Claim 15 is indefinite as it is not clear what are “specific proportions” so as to allow the  
metes and bounds of the claims to be determined.

Claim 13 and 16 are indefinite as it is not clear what is “supertransducing” or  
“supertransduced” so as to allow the metes and bounds of the claims to be determined.

15 Claim 17 is indefinite because it does not further limit claim 1. The use of the term  
“medicament” does not serve to further limit the claim.

Claim 25 is indefinite because it does not further limit claim 23.

Claim 18 is rejected for depending upon an indefinite base (or intermediate) claim.

***Claim Rejections - 35 USC § 112, First Paragraph***

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The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5  
6. Claims 12, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for recombinant multimeric protein, comprising a fusion  
10 polypeptide (linked by disulfide bridges) consisting of monomer A and monomer B of C4BP containing heterologous polypeptides in relation to the alpha and beta chains, does not reasonably provide enablement for medicaments and their uses in therapy or prophylaxis of foetomaternal alloimmunization, viral, bacterial or parasitic infections, disseminated lupus erythematosus, or other alloimmune or autoimmune diseases. The specification does not enable any person skilled in  
15 the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification lists many applications which the protein of the claimed invention might or might be expected to be useful for, including: immunointervention in human immune pathologies (page 3). The specification does not provide any dosage range of the claimed  
20 invention for therapy. The specification has not taught how to treat medical conditions requiring any of the above actions. Although the specification states the object of the present invention is to achieve “immunointervention in the immune pathologies” (page 3, line 14-23), there is no disclosure of any results with the claimed fusion protein in assays, and the actual functional

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properties remain unknown. One skilled in the art cannot predict which fusion proteins might yield positive results. The effect of administration of the claimed fusion protein, which has no disclosed homology with other known proteins, for medical conditions is unpredictable.

Furthermore, using said fusion proteins for therapy or prophylaxis would require undue experimentation.

7. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

The deposit of biological material is considered by the Examiner to be necessary for the enablement of the current invention because the claims require availability of the deposit. The acknowledged deposit of plasmids No. I-1610 and I-1611 (page 5) is not in full compliance with 37 CFR §§ 1.803-1.809 because the specification does not provide a repeatable method for obtaining plasmid No. I-1610 and I-1611 and it does not appear to be a readily available material. An enabled ATCC deposit would satisfy the requirements of 35 USC §112, first paragraph.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating

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that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification. In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

8. Art made of record and not relied upon is considered pertinent to applicants disclosure:

**Reference A** Recombinant proteins S variants deficient in C4BP binding activity, compositions and therapeutic methods.

**Reference B** Chimeric proteins which block complement activation.

**Reference C** Methods of inhibiting complement activation.

9. Claims 1, 3, 4, 20, 23 and 26 allowed.

10. Claims 2, 5-11, 13, 15-16, 20, 22-26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Claims 12 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in this Office action.

#### Advisory Information

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi  
1646  
27 April, 1999



LILA FEISEE  
SUPERVISORY PATENT EXAMINER